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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/821,274

04/07/2004

Michael W. Pantoliano

30923-702.306

9875

27777 7590 02/06/2007
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EXAMINER

ZHOU, SHUBO

ART UNIT

PAPER NUMBER

1631

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/06/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/821,274	Applicant(s) PANTOLIANO ET AL.	
	Examiner Shubo (Joe) Zhou	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/21/06, 1/23/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54-63 is/are pending in the application.
- 4a) Of the above claim(s) 60-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 54-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/17/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendments

Applicant's amendments to the specification filed 11/21/06 are acknowledged and entered. The amendments to the claims filed 1/23/06 are also acknowledged and entered.

Applicant's arguments in response to the previous Office action have been fully considered but they are not deemed to be persuasive. The following rejections and/or objections are either reiterated from the previous Office action, mailed 9/22/05, or newly applied, and constitute the complete set presently being applied to the instant application. Rejections and/or objections not reiterated from the previous Office action are hereby withdrawn.

Claims 54-63 are currently pending, but only claims 54-59 are under consideration. Claims 60-63 have been previously withdrawn from consideration.

Information Disclosure Statement

The Information Disclosure Statement filed 10/17/05 has not been considered because no author names, publication dates for the documents therein have been provided.

Drawings

The replacement sheet for Figures 8A, 8B, 25, 41A and 41B filed 1/23/06 are also acknowledged and accepted.

Specification

The specification is objected to because of the following:

It appears that trademarks are used in this application, such as ROBOCYCLERTM on page 1 and CHEMIIMAGER on page 36. Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

This objection is reiterated from the previous Office action mailed 9/22/05. In the amendments filed 11/21/06, applicant amended the specification to capitalize trademark "ROBOCYCLER," but not CHEMIIMAGER and others. Applicant is requested to review the entire specification to ensure all live trademarks be capitalized.

Appropriate correction is required.

Claim Rejections-35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 54-59 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims are drawn to a method for identifying a ligand that binds to a protein, comprising receiving unfolding data that indicates thermal unfolding as a function of temperature for a protein incubated with a molecule tested for binding; determining an unfolding

temperature for the protein in the presence of the molecule from the unfolding data; comparing the unfolding temperature midpoint for the protein incubated with the molecule with the unfolding temperature midpoint for the protein in the absence of any molecules tested for binding; and determining that the molecule tested for binding binds to the protein when a difference between the unfolding temperature midpoint for the protein in the presence of the molecule and unfolding temperature midpoint for the protein in the absence of any molecules tested for binding exceeds a threshold.

The following analysis of facts of this particular patent application follows the rationale suggested in the "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (OG Notices: 22 November 2005, available from the US PTO website at <http://www.uspto.gov/web/offices/com/sol/og/2005/week47/og200547.htm>).

The Guidelines states:

To satisfy section 101 requirements, the claim must be for a practical application of the § 101 judicial exception, which can be identified in various ways (Guidelines, p. 19):

- The claimed invention "transforms" an article or physical object to a different state or thing.*
- The claimed invention otherwise produces a useful, concrete and tangible result, based on the factors discussed below.*

In the instant case, at least one embodiment of the claimed invention merely manipulates unfolding data etc. All the steps including (1) through (4) of claim 54 could be performed in the combines of a computation device or human mind without communication to the outside world. The process does not seem to transform an article or physical object to a different state or thing outside a computation device or human mind.

Furthermore, at one embodiment of the invention does not produce a useful, concrete and tangible result. Specifically it does not produce a tangible result. Since the process merely

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manipulates data and could be performed in the combines of a computation device or human mind without communication to the outside world, it does not use or make available for use the results of the manipulation to enable its functionality and usefulness to be realized. Thus, at least one embodiment of the claimed invention does not produce a useful and concrete and tangible result.

Double Patenting Rejections

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 54-59 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 71-77 of US copending Application No. 09/801,676.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 54-59 of the instant application are drawn to a method for identifying a ligand that binds to a protein comprising the steps of (1) receiving unfolding data for a protein, (2) determining an unfolding temperature for the protein in the presence of test molecule, (3) comparing the unfolding temperature midpoint for the protein incubated with the test molecule with the unfolding temperature midpoint in the absence of any test molecules, and (4) determining that the test molecule binds to the protein when a difference between the unfolding temperature midpoint for the protein in the presence of the test molecule and the unfolding temperature midpoint in the absence of test molecules exceeds a threshold.

Claims 71-77 of US copending Application No. 09/801,676 are drawn to a method that comprises, *inter alia*, these same 4 steps. Claim 73 also recites fitting data with at least square

algorithm based on an equation, which reads on claims 55-56 of the instant application. Claims 71-77 also recites estimating the ligand binding affinity, which reads on claims 57-58 of the instant application. Claim 74 requires "fluorescence unfolding data" (i.e. $y(T)$ in the equation), which reads on claim 59 of the instant application.

The double patenting rejection is reiterated from the previous Office action mailed 9/22/05. Applicant in the response filed 1/23/06 did not argue against the rejection but requested that the rejection be stayed in abeyance.

Conclusion

No claim is allowed.

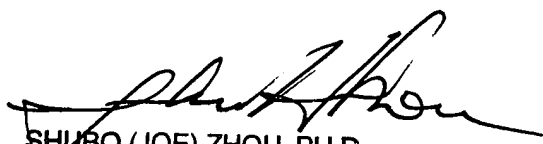
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of

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SHUBO (JOE) ZHOU, PH.D.
PATENT EXAMINER